

Dow AgroSciences LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054

Building 308/2E  
October 17, 2002



Biopesticides and Pollution Prevention Division  
Document Processing Desk (7504C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

Attention: Phil Hutton

*B.t.* CRY34/35Ab1 CONSTRUCT PHP17662 INSECTICIDAL CRYSTAL PROTEIN AS  
EXPRESSED IN MAIZE  
REQUEST FOR NEW EXPERIMENTAL USE PERMIT (68467-EUP-I)

Mycogen Seeds c/o Dow AgroSciences LLC is hereby submitting a new application for an Experimental Use Permit to field test the plant-incorporated-pesticide *B.t.* Cry34/35Ab1 Construct PHP17662. Small scale field tests have shown that *B.t.* Cry34/35Ab1 insecticidal crystal protein (ICP) expressed in maize is very effective in controlling western corn rootworm and northern corn rootworm.

The "active ingredient" in the plant-incorporated-pesticide that is the subject of this EUP is *Bacillus thuringiensis* (*B.t.*) Cry34/35Ab1 Construct PHP17662 insecticidal crystal protein and the genetic material necessary for its production in maize.

This proposed EUP program will cover plantings of *B.t.* Cry34/35Ab1 Construct PHP17662 maize across 16 states from March 2003 to March 2004, for a total of 393.5 acres. The breakdown of acreage in each state and the number of locations in each state is provided in the Proposed Experimental Program, Section G of this submission.

A temporary tolerance petition was previously submitted (March, 2001) and is currently under review at EPA. All activities for this EUP will be conducted on a "non-crop destruct" basis for food and feed use but crop-destruct will be maintained for environmental containment.

Please note that the expression values listed on the Confidential Statement of Formula are research values from research studies conducted either in the field or greenhouse. The purpose of the EUP is to allow more research studies to be conducted to generate the necessary information and data to submit a registration package. Results from GLP-conducted field expression studies will be provided with the full registration package.

We are identifying the confidentiality classification for the studies we are submitting today as 'B'. Additionally, we are identifying the confidentiality classification of the Confidential Statement of Formula, data matrix and proposed labeling as 'C'. The Proposed Experimental Program document has the confidentiality classification of 'A', except for the confidential appendix which is classified as "C".

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Please also note that Pioneer Hi-Bred International has permission to cite the data contained in this submission for their EUP submissions for *B.t. Cry34/35Ab1* (029964-EUP-U; 029964-EUP-L).

**Contents of Submission**

**Volume Number**  
Volume 1  
(Administrative)

**Contents**

**Transmittal document** (this letter)

**Application for Experimental Use Permit to Ship and Use a  
Pesticide for Experimental Purposes Only**, EPA Form 8570-17  
(OPP No. 202684)

**Substantiation for claim of confidentiality** dated October 17, 2002

**Certification with Respect to Citation of Data** (EPA Form 8570-34)  
dated October 17, 2002

**Basic Confidential Statement of Formula** (EPA Form 8570-4) dated  
October 17, 2002

**Data Matrix** for Mycogen Brand *B.t. Cry34/35Ab1* Construct 17662  
Corn (EPA Form 8570-35) dated October 17, 2002 (CBI and CBI  
deleted copies)

**Section A (Product Characterization)**

Data in support of this section is contained in the bridging  
documents entitled "Section A: Product Characterization" and  
Volume(s) 3

**Section B (Proposed Labeling)**

See enclosed proposed labeling for Mycogen Brand *B.t.*  
*Cry34/35Ab1* Construct PHP17662 Corn (Mycogen Brand *Cry34-*  
*35Ab1* Construct PHP17662 Corn/draft/10-17-02) (1 copy)

**Section C (Toxicology Data)**

Data in support of this section is contained in bridging documents  
entitled "Section C: Toxicology Data"

**Section D (Residue and Environmental Data)**

See Study entitled 'SDS-PAGE Sensitivity Analysis for *Cry35Ab1* in  
Support of the Simulated Gastric Fluid Digestion Study  
MRID#45242212' submitted on October 17, 2002 with the request  
for a new experimental use permit for *B.t. Cry34/35Ab1* Construct  
PHP17658 insecticidal crystal protein as expressed in maize  
(68467-EUP-I)

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<b>Volume Number</b>		<b>Contents</b>
		<b>Section E</b> (Product Performance Data and Product Durability Plan) Data in support of this section is contained in bridging document entitled "Section E: Product Performance and Product Durability Plan" and Volume(s) 4
		<b>Section F</b> (Tolerance Proposal) See statement under Section F
		<b>Section G</b> (Proposed Experimental Program) See Volume 2
Volume 2		Proposed Experimental Program Pages: 1-22 (3 copies)
Volume 3	Submitted with 68467-EUP-I (10/17/02)	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant <i>Pseudomonas fluorescens</i> and Transgenic Maize  Schafer, B.W. October 3, 2002 Study ID: GH-C 5545 Pages: 1-17 (3 copies)
Volume 4		Product Characterization Data for <i>Bacillus thuringiensis</i> Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662) Coats, L., Herman, R.A. October 10, 2002 Study ID: PHI-2002-046 Pages: 1-398 (3 copies)

Below is a list of studies, which are being cited for this submission. Some of these studies were submitted today with the request for a new experimental use permit for Cry34/35Ab1 Construct PHP17658 insecticidal crystal protein as expressed in maize (68467-EUP-I) and are classified as confidentiality classification 'B'.

<b>Volume Number</b>	<b>MRID No.</b>	<b>Contents</b>
Volume 5	Submitted 10/17/02	Characterization of DNA Inserted into Transgenic Corn Events E4497.42.1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29 and E4497.71.1.33 Locke, M.E., Nirunsuksiri, W. October 10, 2002 Study ID: GH-C 5550 Pages: 1-26 (3 copies)

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<b>Volume Number</b>	<b>MRID No.</b>	<b>Contents</b>
Volume 6	Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Walbaum Marino, T.A. Study ID: 011193 Pages: 1-31 April 3, 2002 (3 copies)
Volume 7	Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus Marino, T.A. Study ID: 011137 Pages: 1-28 September 5, 2001 (3 copies)
Volume 8	Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> ) Porch, J.R., et al Study ID: 011105 (379-115) Pages: 1-27 September 28, 2001 (3 copies)
Volume 9	Submitted 10/17/02	Assessment of Chronic Toxicity of Diet Containing <i>Bacillus thuringiensis</i> PS149B1 Insecticidal Crystal Protein to Collembola ( <i>Folsomia candida</i> ) Teixeira, D Study ID: 011106 Pages: 1-35 October 9, 2001 (3 copies)
Volume 10	Submitted 10/17/02	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae ( <i>Chrysoperla carnea</i> ) Sindermann, A.B., et al. Study ID: 379-116A Pages: 1-30 November 9, 2001 (3 copies)
Volume 11	Submitted 10/17/02	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212 Herman, R.A., et al Study ID: GH-C 5513 Pages: 1-11 September 9, 2002 (3 copies)
Volume 12	Submitted with this EUP (10/17/02)	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662  Essner, R. Study ID: PHI-2002-048 Pages: 1-110 October 14, 2002 (3 copies)

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<b>Volume Number</b>	<b>MRID No.</b>	<b>Contents</b>
Volume 13	Submitted 10/17/02	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1 Storer, N.P. Study ID: GH-C 5506 Pages: 1-14 September 26, 2002 (3 copies)
Volume 14	Submitted 10/17/02	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms Higgins, L. Study ID: PHI-2002-056 Pages: 1-12 October 11, 2002 (3 copies)
	45242207	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. Study ID: 001130 October 10, 2000
	45242204	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study Herman, R.A. Study ID: 000366 (GH-C 5114) September 26, 2000
	45242208	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. Study ID: 001129 October 10, 2000
	45242209	PS149B1 14 KDA and 44 KDA Proteins: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. Study ID: 001128 October 10, 2000
	45242212	<i>In Vitro</i> Digestibility of PS149B1 Proteins Korjagin, V.A. and Ernest, A.D. Study ID: 000302 (GH-C 5132) October 6, 2000
	45584502	<i>In Vitro</i> Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein Korjagin, V.A. et al. Study ID: 010111 (GH-C 5361) January 8, 2002

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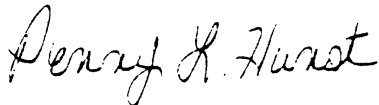
Volume Number	MRID No.	Contents	
	45242205	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens Stelman, S.J. Study ID: GH-C 5140	October 13, 2000
	45358401	Thermolability of PS149B1 Binary Delta-Endotoxin Herman, R. Study ID: 001041	March 19, 2001
	45584501	Heat Lability of Individual Proteins of the PS149B1 Binary ICP Herman, R. Study ID: 010144 (GH-C 5360)	January 7, 2002
	45340701	Microbial PS149B1 Binary Insecticidal Crystal Protein. Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein. and Individual PS149B1 14kDa and 44kDa Insecticidal Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development Maggie, V. Study ID: CAR 149-00	January 28, 2001
	45242210	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle Bryan, R.L., et al Study ID: 379-103 (000155)	September 3, 2000
	45242211	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle Higgins, L. Study ID: PHI-2000-022	October 6, 2000
	45360201	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate Bryan, R., et al Study ID: 379-104	March 19, 2001
	45242214	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region Herman, R.A., et al Study ID: 000365 (GH-C 5113)	October 15, 2000

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We request that our application be reviewed in sufficient time to grant approval by spring planting in March 15, 2003.

If you require further information, please contact me at 317-337-3977 or Jill Achor, Registration Assistant, at 317-337-4660.

Regards,



Penny L. Hunst, Ph.D.  
Regulatory Manager  
Regulatory Success-Americas

PLH/jea  
Enclosures

cc: Michael Mendelsohn (including one copy of Section G)  
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